DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 20, 2015

Medisim, Ltd.
Mr. Avi Ben Yaish
QA Manager
G.G. Communication Center
Neve Ilan
ISRAEL 90850

Re: K150160
Trade/Device Name: Temple Touch Pro™ (TTP™) – Temperature monitoring system
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 6, 2015
Received: September 9, 2015

Dear Mr. Ben Yaish:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150160

Device Name
Temple Touch Pro™ (TTP™) – Temperature monitoring system

Indications for Use *(Describe)*
The TTP™ is a non-sterile temperature monitoring system intended to measure and monitor core body temperature of patients of all ages, by applying a sensor unit on the forehead.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5 - 510(k) Number K150160 Summary

Medisim Ltd.

Temple Touch Pro™ (TTP™) - Temperature Monitoring System

Applicants Name:

Medisim Ltd.

G.G. Communication Center

Neve Ilan 90850, Israel

Tel: 972-2-9950-619

Fax: 972-2-579-1926

Contact Person:

Avi Ben Yaish

aviby@medisim.co.il

Date Prepared: 20 OCT 2015

Trade Name of the device subject to this submission:

Temple Touch Pro™ (TTP™) - Temperature Monitoring System

Common name: Clinical, Electronic thermometer

Classification Name: Clinical Electronic Thermometer

Classification: Clinical Electronic Thermometers are class II devices, 20 CFR 880.2910.

Classification Panel: General Hospital (Part 880 in the 21 CFR)

Indication for Use:

The TTP™ is a non-sterile temperature monitoring system intended to measure and monitor core body temperature of patients of all ages, by applying a sensor unit on the forehead.

Description of the device

The TTP™ system monitors the body core temperature through continuous measurements of the patient. The system is non-sterile and comprised of a disposable Sensor Unit, attached to the patient temple, and connected to a Monitor Connecting Unit which is connected to a power supply and to any YSI-400 input vital signs monitor, through which, the patient temperature is presented. The MCU is able to present the patient temperature as a standalone unit.

Statement of substantial equivalence:

The TTP™ is substantially equivalent to 3M SpotOn Temperature monitoring system (Arizant healthcare Inc.) cleared under K120412.

For convenience, the various similarities and differences are presented in the substantial equivalence comparison table and summarized below:

	TTP™	**3M SpotOn (Arizant healthcare Inc.)**
510(k) number		K120412
Manufacturer	Medisim Ltd.	3M (Arizant healthcare Inc.)
Device name	Temple Touch Pro™	SpotOn
Intended use	Measure and monitor core body temperature of patients of all ages, by applying a sensor unit on the forehead.	Measure, monitor, and trend body temperature of adult and pediatric patients.
Components	• Sensor Unit (SU) • Sensor Unit Cable • Monitor Connecting Unit (MCU) • Power Supply	• Temperature Sensor • Sensor Cable • Control Unit • Power Supply
Measurement Technology	TTP ™ system uses heat flux technology to measure the patient's body core temperature. The Sensor Unit is attached to the skin above the temporal artery. The system utilizes double layer sensor to measures the heat flux and derive the core temperature. Once the temperature is calculated, the TTP	The 3M SpotOn system uses zero-heat-flux thermometry to measure the patient's core temperature. The 3M SpotOn system warms the sensor (attached to the skin), creating an isothermal zone under the sensor. Once equilibrated to the core temperature, a zero-heat-flux condition is established. When the

	displays a noninvasive measurement of the patient's core temperature.	temperature sensor reaches equilibrium with the patient's core temperature, the 3M SpotOn displays a noninvasive measurement of the patient's core temperature.
Output to hospital monitor	compatible with YSI400	compatible with YSI400
Sensor/s	Thermistor	Thermistor
Measurement location	Patient's temple area of the forehead	Patient's forehead above the orbital ridge
Temperature measurement range	25°C - 45°C (77°F - 113°F)	25°C - 43°C (77°F - 109°F)
Accuracy	± 0.2°C	± 0.2°C
Reusable/ Disposable	Disposable ,non-sterile	Disposable ,non-sterile

The similarities and differences between TTP™ device and its predicate:

The devices are similar in:

- Intended use (measure & monitor body temperature)
- System components (sensor, control/connecting unit, cables, power supply)
- Technological characteristics (incorporating heat conduction & heat flux method)
- Sensor type (thermistor)
- Place of measurement (both TTP's and 3M SpotOn's sensors are placed on the forehead skin surface).
- Both systems transmitting the output to any YSI400 compatible patient monitor and are also able to present the temperature on their' standalone display units.

The devices are different in:

	TTP™	**3M SpotOn** (Arizant healthcare Inc.)
Temperature determination principal	Heat flux from the tissue, to the sensor is measured and used to, calculate (determine) the body temperature.	Applying zero-heat flux principal by locally heating the tissue at the measuring site, is used to determine the body temperature.

Non-Clinical and Clinical Device Testing (Software Validation, Bench & Clinical test)

The TTP was tested and evaluated in order to fully validate its performance:

A. Software Validation Tests

B. Performance testing :

1. Bench testing according to ASTM E-1112-00
2. Clinical testing through a clinical study according to ISO80601-2-56 .

A. Software Validation:

The software was validated to assure the full functionality of the TTP.

The device software was validated successfully as device is fully function.

B. Performance testing:

B. 1. Bench testing

Bench testing was performed in accordance to ASTM E-1112-0.0

The device passed all bench tests successfully as it withstands acceptance criteria for each and every bench test performed.

B.2 Clinical Study

This clinical trial was performed in compliance with ISO 80601-2-56 and GCP standards.

The purpose of the clinical study was to demonstrate there is no statistically significant difference between temperatures measured by Temple Touch Pro™ and by other invasive thermometers.

In order to achieve this goal the trial was conducted among various populations (different age groups, genders and operations) and compared to various reference measurements.

Subjects were 95 males and 86 females in the ages 0-73 years old (median age was 4), Total subjects were 181, and total samples of 4591.

There were no observations or reports of adverse effects. The TTP™ was found to be as reliable as other clinical thermometers.

The compliance of the new device and the predicate device has been assessed and validated against the standards below:

- **IEC60601-1(2005, 3 Ed)** Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
  IEC60601-1-2 (2007, 3 Ed) Medical electrical equipment – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- **ISO 14971(2007, 2 Ed)** - Medical devices- Application of risk management to medical devices.
- **ISO 10993-10**, Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization.
- **ISO 10993-5**, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- **ASTM E 1112-00 (2006) 3 RD** Electronic thermometer for intermittent determination of patient temperature.
- **ISO 80601-2-56**:**1ST 2009** Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
- **EN 12470-4:2009-11** – Performance of electrical thermometers for continuous measurement.

Conclusion:

The subject product was found substantially equivalent to the legal predicate device based on the results from the performance testing and the clinical investigation.